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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/813,852 | 03/30/2004 | David R. Scholl | DHI-08810 | 8488 |

7590 12/30/2004

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| EXAMINER | |
|---|---|
| SALIMI, ALI REZA | |
| **ART UNIT** | **PAPER NUMBER** |
| 1648 | |

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/813,852 | SCHOLL ET AL. | |
| | Examiner | Art Unit | |
| | A R Salimi | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *5-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-34 are pending.
Raw Sequence Listing have been entered.
Submitted Information Disclosure Statement (I.D.S) is noted.

### *Election/Restrictions*

Applicant's election without traverse of Group I (claims 1-4) in the reply filed on 11/12/04 is acknowledged.

Claims 5-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups. Election was made **without** traverse in the reply filed on 11/12/04.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (Journal of Virological Methods, 1992, Vol. 39, pages 39-46).

The teaching of the above cited art anticipates the claimed invention. Lee et al disclosed a composition comprising of cell culture MDCK and A549 (see page 41, 2nd full paragraph). The composition disclosed by Lee et al is the same as now claimed composition.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brumback et al (Journal of Clinical Microbiology, 1996, Vol. 34, No. 4, pages 798-801), and Hierholzer et al (Journal of Clinical Microbiology, 1993, Vol. 31, No. 6, pages 1504-1510).

The claimed invention is directed to a composition comprising a mixed cells culture comprising MDCK cells and H292 cells.

Brumback et al taught mixture of MDCK cells and RMK cells and showed that combination proved sensitive in detection of influenza virus (see the abstract, and page 801, left column, 1st full paragraph). This only differs since they did not mix H292 cells with MDCK cells.

Hierholzer et al taught NCI-H292 cells and disclosed that the said cells are sensitive for growth and detection of broad range of viruses (see the abstract, and page 1509, right column, last full paragraph).

Thus, one of ordinary skill in the art at the time of filing would have been highly motivated by the above teaching to mix MDCK cells with H292 cells to be used in detection of viruses or growth of various virus types. Hierholzer et al had already taught H292 could be a

viable substitute to other cells for viral growth and detection. In addition, Brumback et al had also disclosed that MDCK can be mixed with another cell type which not only prove efficacious but rather the mixture proved to be even more sensitive. Hence, substituting RMK with H292 would have been within purview of one of ordinary skill in the art absent unexpected results. Thus, the invention as a whole is prima facie obvious absent unexpected results.

Claims 1, and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (Journal of Virological Methods, 1992, Vol. 39, pages 39-46), and Hierholzer et al (Journal of Clinical Microbiology, 1993, Vol. 31, No. 6, pages 1504-1510).

As stated above Lee et al disclosed a composition comprising of cell culture MDCK and A549 (see page 41, 2nd full paragraph). This only differs since they did not further add H292 cells.

Hierholzer et al taught NCI-H292 cells and disclosed that the said cells are sensitive for growth and detection of broad range of viruses (see the abstract, and page 1509, right column, last full paragraph).

Hence, one of ordinary skill in the art at the time of filing would have been highly motivated by the above teaching to mix MDCK and A549 cells with H292 cells to be used in detection of viruses or growth of various virus types. Hierholzer et al had already taught H292 could be a viable substitute to other cells for viral growth and detection. In addition, Lee et al had also disclosed that MDCK could be mixed with another cell type such as A549. Hence, adding another well-known cells such as H292 with MDCK and A549 would have been within

purview of one of ordinary skill in the art absent any unexpected results. All the elements of the claimed invention are taught in the prior art, their efficacy as a mixture and capability of surpassing detectability and/or viral growth is also shown in the prior art. Hence, it would have been obvious for one of skill in the art to mix all three well-defined cells to be able to use the cell mixture in a detection assay. There are no facts in the disclosure that shows any observance of unexpected results at the time of filing. Thus, the invention as a whole in light of the above cited art is deemed prima facie obvious absent unexpected results.

**Applicants are reminded that the priority for the claimed invention and rejections made below is determined to be the date of filing for this application, 03/30/2004. The newly claimed invention was not present in the prior Applications. If Applicants disagree with this determination, please point to specific pages of a priority document(s) that provides support for the now claimed invention. In addition, if applicants disagree with the determination please provide specific reasoning why the claims are entitled to priority prior to 03/30/2004.**

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brumback et al (Journal of Clinical Microbiology, 1996, Vol. 34, No. 4, pages 798-801), and Huang et al (Journal of Clinical Microbiology, January 2000, Vol. 38, No. 1, pages 422-423).

The claimed invention is directed to a composition comprising a mixed cells culture comprising MDCK cells and A549 cells.

Brumback et al taught mixture of MDCK cells and RMK cells and showed that combination proved sensitive in detection of influenza virus (see the abstract, and page 801, left column, 1st full paragraph). This only differs since they did not mix A549 cells with MDCK cells.

Huang et al taught mixture of Mink lung cells and A549 cells provided synergistic effect for detection of influenza virus (see the abstract).

Therefore, one of ordinary skill in the art at the time of filing would have been highly motivated by the above teaching to mix MDCK cells with A549 cells to be used in detection of viruses. Huang et al had already taught A549 mixture with Mink Lung cells would provide synergistic effect for viral growth and detection. In addition, Brumback et al had also disclosed that MDCK can be mixed with another cell type which not only prove efficacious but rather the mixture proved to be even more sensitive. Hence, substituting RMK with A549 or substituting Mink Lung cells with MDCK to obtain a slightly different mixture would have been within purview of one of ordinary skill in the art absent unexpected results. Thus, the invention as a whole is prima facie obvious absent unexpected results.

Claims 1, 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brumback et al (Journal of Clinical Microbiology, 1996, Vol. 34, No. 4, pages 798-801), and Huang et al (Journal of Clinical Microbiology, January 2000, Vol. 38, No. 1, pages 422-423), in view of Hierholzer et al (Journal of Clinical Microbiology, 1993, Vol. 31, No. 6, pages 1504-1510).

Brumback et al taught mixture of MDCK cells and RMK cells and showed that combination proved sensitive in detection of influenza virus (see the abstract, and page 801, left column, 1st full paragraph). This only differs since they did not mix A549 cells with MDCK and H292 cells.

Huang et al taught mixture of Mink lung cells and A549 cells provided synergistic effect for detection of influenza virus (see the abstract). This only differs since they did not mix A549 cells with MDCK and H292 cells.

Hierholzer et al taught NCI-H292 cells and disclosed that the said cells are sensitive for growth and detection of broad range of viruses (see the abstract, and page 1509, right column, last full paragraph).

Therefore, one of ordinary skill in the art at the time of filing would have been highly motivated by the above teaching to mix MDCK cells with A549 cells to be used in detection of viruses as the mixture of the cells already proven a viable choice in inducing a significant viral detection as taught by Huang et al and Brumback et al. In addition, Hierholzer et al had also

disclosed that H292 is a viable cell type for viral growth. All the elements of the claimed invention are taught in the prior art, their efficacy as a mixture and capability of surpassing detectability and/or viral growth is also shown in the prior art. Hence, it would have been obvious for one of skill in the art to mix all three well-defined cells to be able to use the cell mixture in a detection assay. There are no facts in the disclosure that shows any observance of unexpected results at the time of filing. Thus, the invention as a whole in light of the above cited art is deemed prima facie obvious absent unexpected results.

No claims are allowed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be

obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

12/29/2004